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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/401,004

Applicant(s)

Lang et al.

Examiner

Grace Hsu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 21, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) 1-15, 23-25, and 27-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-22 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO 413) Paper No(s).
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5812 20) ☐ Other:

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DETAILED ACTION

1. A Petition for a Four Month Extension of Time and A Response to Restriction Requirement, respectively received May 21, 2001, were entered as Paper Nos. 13-14.

Status of Claims

2. 1-34 are pending in the current application.
3. Claims 16-22 and 26 are under examination in the current application.
4. Claims 1-15, 23-25 and 27-34 are withdrawn from further consideration by the Examiner under 37 C. F. R. 1.142(b), as being drawn to a non-elected inventions, the requirement having been traversed in Paper No. 14.

Election/Restriction

5. Applicants election with traverse of:

[1] Group II, claims 16 to 30, directed to a single benzimidazole compound; and

[2] a species election of the benzimidazole core structure of claim 16,
wherein: R^1 , R^2 and R^4 are hydrogen;

R^3 is the formula $-C(O)NR^{11}R^{12}$, wherein R^{11} and R^{12} are hydrogen;

R^5 is 3-phenoxyphenyl (i.e., C_6H_5 -substituted at the 3-position with a $-OC_6H_5$ moiety;

R^6 is methylenemethylene (i.e., by this term applicants are believed to have indicated a " CH_2-CH_2 " group; however, conventionally organic art defined nomenclature indicates that the term "methylenemethylene" is equivalent to " CH_3CH_2- " moiety); and

R^7 and R^8 are hydrogen.

for examination purposes is acknowledged.

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6. Applicants' traversal was made on the ground that no serious search burden exists for the Examiner, because [1] the inventions are not distinct as they are directed to the same inventive concept; [2] there is no undue search burden as restriction is not required; and that [3] election of species is not required as adequate support was not provided with this restriction.

In response, applicants' arguments are found non-persuasive. The Examiner maintains that an undue search burden exists, because divergent searches are required for the inventions of Groups I-III. In particular, the inventions of Groups I-III are classified in different classification and subclassifications (Group I is classified in class 436, subclass 536, Group II is classified in class 548, subclass 305.1 and Group III is classified in 436, subclass 518) which are directed to different inventions with different inventive concepts, which would require different and divergent searches of the patent and non-patent literature.

In light of the above, the aforementioned groups represent patentably distinct subject matter directed to different inventions of the inventive concept, that require divergent searches of the patent and non-patent literature, because of different issues regarding patentability and enablement (as those respective inventions relate to different compounds, compositions and methods and processes involving different steps for different purposes). In the instant case, applicants filing of one application claiming more than one invention imposes an administrative burden on the patent office to examine plural inventions in a single application.

The requirement is still deemed proper and is therefore made FINAL.

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7. Claims 1-15, 23-25, 27-20 and 31-34 are withdrawn from further consideration by the Examiner under 37 C. F. R. 1.142(b), as being drawn to a non-elected inventions, the requirement having been traversed in Paper No. 14.

Allowable Subject Matter

8. The following is a statement of reasons for the indication of allowable subject matter:

The elected species is deemed free of the prior art and a claim, drawn exclusively to the elected species would be allowable.

The search has been expanded to encompass the remaining non-elected species, as provided for under current Markush examination practice at the discretion of the Examiner.

Specification

9. The disclosure is objected to because of the following informalities.

10. The disclosure is objected to for unclear chemical structure drawings or figures in the chart as set forth on pages 88-97, which correspond to the written description of Example 8 of the instant specification, wherein the chemical drawing structures are unclearly depicted as certain atoms and functional group moieties are obscured, overlap, etc. with other moieties on the printed page. Applicants are requested to furnish copies of clear representations of the chemical structures of the aforementioned chart in the specification. Appropriate clarification is requested.

11. The disclosure is objected to for the use of numerous erroneous nomenclature terms used to define certain functional group substituents that are inconsistent with what is conventionally

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used in the art, resulting in distortions in interpretations of the claims as there is more than one understood meaning for certain nomenclature terms cited in the claims.

For example, the conventional organic nomenclature conventionally uses the suffix “ene” to define or indicate a olefinic structure, i.e., “-C=C-” moiety. In light of the foregoing, confusion in claim interpretation may result when the reader reads in claim 16, the recitation of the terms C2 to C12 substituted alkenyl versus in claim 20 the recitation of the term C1-C12 alkylene. In addition, while applicants have defined in the specification the intent of the usage of the suffix “ene” via its addition to the end of certain functional group terms in the specification (i.e., see page 19, lines 14-20) to mean:

“the suffix “ene” added to any of the described terms means that two parts of the substituent are each connected to two other parts in the compound (unless the substituent contains only one carbon, in which case such carbon is connected to two other parts in the compound, for example, methylene”

is nevertheless misleading as an ordinary artisan would interpret certain functional moieties as based upon applicants nomenclature definitions to be inconsistent with conventional organic chemistry art nomenclature usage. For example certain of the terms recited in the instant claims would be interpreted to have improper chemical valency issues; i.e., e.g., the species “phenylene” as recited in the claims may conventionally be understood to be a unstable chemical species due to disruption of the aromaticity of an aromatic benzene or phenyl group. Clarification is requested. (Also see, *In re Barr*, 170 USPQ 330 (C.C.P.A. 1971).

12. Appropriate correction of the above-identified issues are requested.

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Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 16-22 and 26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-22 and 26 are vague and indefinite in that there are numerous erroneous nomenclature terms used to define certain functional group substituents that are inconsistent with what is conventionally used in the art, resulting in distortions in interpretations of the claims as there is more than one understood meaning for certain nomenclature terms cited in the claims. It is unclear what certain nomenclature terms refer to, as the metes and bounds of the aforementioned claim cannot be determined as the specification, claims and art do not recognize what claim functional group terminology inconsistent with art established chemical nomenclature.

For example, the conventional organic nomenclature conventionally uses the suffix “ene” to define or indicate a olefinic structure, i.e., “-C=C-” moiety. In light of the foregoing, confusion in claim interpretation may result when the reader reads in claim 16, the recitation of the terms C2 to C12 substituted alkenyl versus in claim 20 the recitation of the term C1-C12 alkylene. In addition, while applicants have defined in the specification the intent of the usage of

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the suffix "ene" via its addition to the end of certain functional group terms in the specification (i.e., see page 19, lines 14-20) to mean:

"the suffix "ene" added to any of the described terms means that two parts of the substituent are each connected to two other parts in the compound (unless the substituent contains only one carbon, in which case such carbon is connected to two other parts in the compound, for example, methylene"

is nevertheless misleading as an ordinary artisan would interpret certain functional moieties as based upon applicants nomenclature definitions to be inconsistent with conventional organic chemistry art nomenclature usage. For example certain of the terms recited in the instant claims would be interpreted to have improper chemical valency issues; i.e., c.g., the species "phenylene" as recited in the claims may conventionally be understood to be a unstable chemical species due to disruption of the aromaticity of an aromatic benzene or phenyl group. (Also see, *In re Barr*, 170 USPQ 330 (C.C.P.A. 1971).

In light of the foregoing, clarification is requested.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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16. Claims 16-22 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO International Appln No. 97/10219 (herein referred to as WO Appln. '219, International Publication date: March 20, 1997.

The claimed invention is directed to a single benzimidazole compound of formula (I) (with functional group substituents are identified at specific positions on the core ring according to conventional organic nomenclature numbering, which indicates that the claimed benzimidazole core ring is substituted at position 1 (i.e., with nitrogen atom 1 attached to the substituent-R₆-C(O)-NR₇R₈), position 2 (with the substituent R₅), position 4 (with the substituent R₄), position 5 (with the substituent R₃), position 6 (with the substituent R₂) and position 7 (with the substituent R₁), with no substitution at the nitrogen of position 3 and carbons 8 and 9 are bridgehead carbons).

WO Appln. '219 discloses: [1] a benzimidazole core ring compound and corresponding derivative compounds, which anticipates the claimed invention; [2] wherein said core ring structure has functional group substituents that correspond to functional group substituents positions on the benzimidazole ring core of the claimed invention; note that the direct functional group substituent group correspondence is identified below, i.e.,

<u>WO'219 Core Ring Substituents</u>	<u>Position Corresponds To</u>	<u>Claimed Benzimidazole Core Ring Positions</u>
R1	Position 1	substituent-R ₆ -C(O)-NR ₇ R ₈)
R2	Position 2	substituent R ₅
No substitution	Position 3	No substitution
A-R ₄	Position 4	substituent R ₄
R ₃ or Hydrogen	Positions 5-7	R ₃ , R ₂ , R ₁

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[3] wherein the substituent definitions defined in the instant reference read on those definitions defined in the claimed invention and anticipate the benzimidazole compounds of the claimed invention.; and [4] see Example 1-91 of compounds therein that read on the claimed invention (see, pages 24-128)

Therefore, WO Appln. '219 anticipates the claimed invention.

17. Claims 16-22 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO International Appln No. 99/40072 (herein referred to as WO Appln. '072, International Publication date: August 12, 1999).

WO Appln. '072 discloses: [1] a benzimidazole core ring compound and corresponding derivative compounds, which anticipates the claimed invention; [2] wherein said core ring structure has functional group substituents that correspond to functional group substituents positions on the benzimidazole ring core of the claimed invention; i.e.,

<u>WO '07 ring substituent</u>	<u>position corresponds to</u>	<u>Claimed Benzimidazole Core Ring Positions</u>
X, which includes a N	Position 3	Nitrogen
Y, which includes NR ₂	Position 1	Nitrogen Substituted w/substituent-R ₆ -C(O)-NR ₇ R ₈)
A-Ar-Rc	Position 2	substituent R ₅
Ra or Rb -no position indicated in generic core	Position 4	substituents R ₄ , R ₃ , R ₂ , R ₁

[3] wherein the substituent definitions defined in the instant reference read on those definitions defined in the claimed invention and anticipate the benzimidazole compounds of the claimed invention; and [4] see Example 1-281 of compounds therein that read on the claimed invention (see, pages 51-203)

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Therefore, WO Appln. '072 anticipates the claimed invention.


Status of Claims

18. No claims are allowed in the above-identified application.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Grace C. Hsu, Ph.D., J.D. whose telephone number is (703) 308-7005. The Examiner may be reached during normal business hours, Monday through Friday from 8:30 am to 6:00 pm (EST). A message may be left on the Examiner's voice mail.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jyothsna Venkat, Ph.D., may be reached at (703) 305-0570. The fax number assigned to Group 1618 is (703) 305-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1618 receptionist whose telephone number is (703) 308-0196.


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Grace C. Hsu, Ph.D.

July 15, 2001